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10/006,780	11/30/2001	Roman Sakowicz	CYTOP083	9903

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
BASKAR, PADMAVATHI	

ART UNIT	PAPER NUMBER
1645	11

DATE MAILED: 12/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/006,780	Applicant(s) SAKOWICZ ET AL.	
	Examiner Padmavathi v Baskar	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *9/19/03*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-15,17 and 18* is/are pending in the application.

4a) Of the above claim(s) *17 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's response to restriction requirement filed on 9/19/03 in Paper # 9 is acknowledged. Claims 1-7 and 16 have been cancelled. Claims 8-10, 15 and 17 have been amended. Claims 1-18 are pending in the application.

Specification - Informalities

2. The specification is replete with terms, which are not clear and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Example of some unclear, inexact terms used in the specification are as follows:

The specification on page 16 in paragraph # 0066 cites a blank PCT application number and needs to be corrected with a proper application number.

The specification on page 19, paragraph 0074 refers to Figure 2, however, no figures and Brief Description of figures are present in the specification.

The specification on page 46 paragraph # 00191 refers to a SDS-PAGE gel and 50 KD protein, however there is no drawing or figure in the application.

Finally the specification on page 47, paragraph # 00189 refers to a table, however, no table is present. Therefore, Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Election

3. Applicant's election of Group II, claims 8-15 drawn to a protein, SEQ ID NO: 2, in Paper # 9 (9/19/03) with traverse is acknowledged. The traversal is on the grounds that the restriction requirement of single disclosed SEQ.ID.NO is not proper as SEQ.ID.NO: 4, 6, 8 and 10 are fragments of SEQ.ID.NO: 2. The examiner will examine the claims 8-15 with respect to SEQ.ID.NO: 2, 4, 6, 8 or10 as they are part of SEQ.ID.NO: 2. Applicant also requests the office to rejoin the method claims 17 and 18. However, if a product claim is subsequently found

allowable, withdrawn process claims 17-18 that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

4. Claims 17-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Applicant timely traversed the restriction (election) requirement in Paper #. 9

Information Disclosure Statement

5. The Information Disclosure Statement filed on 9/29/03 Paper # 10 is acknowledged and a signed copy of the same is enclosed to this office action.

Claim Rejections - 35 USC 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying

7. Claims 8-10 and 12-15 are rejected under 35 U.5.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is referred to the interim guidelines on written description published June 15, 1998 in the Federal Register at Volume 63, Number 114,

pp 32639-32645 (also available at www.uspto.gov). This is a written description rejection.

The claims are drawn to an isolated protein, wherein the protein comprises a sequence that has greater than 90% amino acid sequence identity to SEQ.ID.NO: 2, 4, 6, 8 or 10 as measured using a sequence comparison algorithum and (b) microtubule stimulated ATpase activity and the protein binds to polyclonal antibodies raised against said protein.

The specification broadly describes as part of the invention, an isolated recombinant kinesin motor protein of SEQ ID NO: 2, which is encoded by SEQ.ID.NO: 1 from *Plasmodium falciparum* merozoites. The specification teaches that this full-length protein contains 1288 amino acids and has microtubule stimulated ATPase activity and depolymerizes microtubules. This protein could be useful in diagnosis, prevention and treatment of malaria. It appears that the amino acid sequences SEQ.ID.NO: 4 (332 amino acids) SEQ.ID.NO: 6 (355 amino acids), SEQ.ID.NO: 8(361 amino acids) and SEQ.ID.NO: 10 (332 amino acids) are the proteins obtained from the full-length protein SEQ.ID.NO: 2. However, the specification does not teach isolated proteins, SEQ.ID.NO: 4, 6, 8, or 10 having microtubule stimulated ATPase activity and/or depolymerizes microtubules and an isolated protein comprising a sequence that has greater than 90% amino acid sequence identity to SEQ.ID.NO: 2, 4, 6, 8 or 10. Applicants broadly describe the invention as embracing any deletion by use of language in which a specified percent of amino acids can be changed in the protein. USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that (he or she] invented what is claimed." (See Vas-Cath at page 1116).

Thus, an isolated protein comprising the amino acid sequence of SEQ ID NO: 2 having microtubule stimulated ATPase activity and/or depolymerizes microtubules meets the written description provision of 35 U.S.C. 112, first paragraph for the reasons set forth below.

The specification fails to teach an isolated protein SEQ.ID.NO: 4, 6, 8, or 10 having microtubule stimulated ATPase activity and/or depolymerizes microtubules and an isolated protein comprising a sequence that has greater than 90% amino acid sequence identity to SEQ.ID.NO: 2, 4, 6, 8 or 10 and is noted that the claimed fragments do not exist as an invention independent of their function

The actual relevant identifying characteristics of each protein having the claimed properties (kinesin motor protein activity) of the protein can only be determined empirically by actually making every nucleic acid that encodes the recited fragments and testing each to determine whether such a fragment having the particularly disclosed properties of full length protein. For example, if there is a well-established correlation between structure and function in the art, one skilled in the art will be able to reasonable predict the complete structure of the claimed invention from its function. This specification does not teach such, and the art is devoid of this correlation for an isolated protein SEQ.ID.NO: 4, 6, 8 or 10 having microtubule stimulated ATPase activity and/or depolymerizes microtubules and an isolated protein comprising a sequence that has greater than 90% amino acid sequence identity to SEQ.ID.NO: 2, 4, 6, 8 or 10 with undetermined function. There is no written description support for an isolated protein, SEQ.ID.NO: 4, 6, 8, or 10 and having microtubule stimulated ATPase activity and/or depolymerizes microtubules and an isolated protein comprising a sequence that has greater than 90% amino acid sequence identity to SEQ.ID.NO: 2, 4, 6, 8 or 10 as claimed.

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 U5PQ2d

1601, 1606 (CAFC 1993) and Amgen Inc V Chugai Pharmaceutical Co Ltd., 18 U5PQ2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 U5PQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class.

8. Claims 8-10 and 11-15 are rejected under 35 U.5.C. 112, first paragraph, because the specification, while being enabling for an isolated polypeptide comprising the amino acid sequence SEQ ID NO: 2 having microtubule stimulated ATPase activity and/or depolymerizes microtubules, does not reasonably provide enablement for an isolated protein comprising SEQ.ID.NO: 4, 6, 8 or 10 and having microtubule stimulated ATPase activity and/or depolymerizes microtubules, an isolated protein comprising a sequence that has greater than 90% amino acid sequence identity to SEQ.ID.NO: 2, 4, 6, 8 or 10 and The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly, connected, to make and use the invention commensurate in scope with these claims.

The specification teaches the recombinant kinesin motor protein, SEQ.ID.NO: 2 from merozoites of Plasmodium falciparum. The specification discloses the claimed protein could be used as target protein for measuring ATPase activity and microtubule depolymerizing activity etc (pages 46-48). However an isolated protein, SEQ.ID.NO: 4, 6, 8 or 10 having microtubule stimulated ATPase activity and/or depolymerizes microtubules and an isolated protein comprising a sequence that has greater than 90% amino acid sequence identity to SEQ.ID.NO: 2, 4, 6, 8 or 10. Moreover, protein chemistry is probably one of the most unpredictable areas of biotechnology and the art teaches that the significance of any particular amino acid sequences (i.e. fragments) for different aspects of biological activity cannot be predicted a priori and must be determined empirically on a case-by-case basis (Rudinger et al, in "PEPTIDE HORMONES", edited by Parsons, J.A., University Park Press, June 1976, page 6). The art specifically teaches

that even a single amino acid change in a protein leads to unpredictable changes in the biological activity of the protein. For example, replacement of a single lysine residue at position 118 of the acidic fibroblast growth factor by glutamic acid led to a substantial loss of heparin binding, receptor binding, and biological-activity of the protein (Burgess et al., The Journal of Cell Biology, 111:2129-2138, 1990). In transforming growth factor alpha, replacement of aspartic acid at position 47 with alanine, or asparagine did not affect biological activity while replacement with serine or glutamic acid sharply reduced the biologic activity of the mitogen (Lazar et al., Molecular and Cellular Biology, 8(3): 1247-1252, 1988). These references demonstrate that even a single amino acid substitution or what appears to be an inconsequential chemical modification, will often dramatically affect the biological activity of a protein. Proteins with replacement of single amino acid residues may lead to both structural and functional changes in biological activity and immunological recognition. For example, Jobling et al. (Mol. Microbiol. 1991, 5(7): 1755-67 teaches a panel of single amino acid substitutions by oligonucleotide directed mutagenesis which products proteins that differ in native conformation, immunological recognition, binding and toxicity, thus exemplifying the importance of structural components to both biological function and immunological recognition. Applicants have not taught an isolated protein SEQ.ID.NO: 4, 6, 8, or 10 having microtubule stimulated ATPase activity and depolymerizes microtubules and an isolated protein comprising a sequence that has greater than 90% amino acid sequence identity to SEQ.ID.NO: 2, 4, 6, 8 or 10 that is functional as an immunogenic composition or is capable of use as a diagnostic using immunological means of recognition. Since, the specification lacks a written description of isolated protein SEQ.ID.NO: 4, 6, 8, or 10 having microtubule stimulated ATPase activity and depolymerizes microtubules and an isolated protein comprising a sequence that has greater than 90% amino acid sequence identity to SEQ.ID.NO: 2, 4, 6, 8 or 10, it is not enabled for this language

because it fails to enable the skilled artisan to envision the detailed structure and function of the claimed proteins. In view of the unpredictability of the art, the lack of teachings of the specification, it would require undue experimentation on the part of the skilled artisan to practice the invention as claimed.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 11-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Ristic et al U.S.Patent 4,767,622.

Ristic et al disclose vaccine compositions for use in developing protective immunity against infection by Plasmodium parasites. Soluble proteinaceous immunogens are isolated from the fluid culture medium of in vitro propagated plasmodial species parasites (P.falciparum) in mammalian erythrocyte culture supernatant or from washes, including hypotonic washes, of cultured erythrocytes parasitized by plasmodium. Immunogens so obtained have molecular weights in the range from about 35,000 daltons to about 85,000 daltons (see abstract and Example 3 and 4). These immunogens read on the claimed isolated protein comprising an amino acid sequence SEQ.ID.NO: 2 (1, 4, 6, 8 and 10) because the immunogens are isolated from P.falciparum merozoite and contain proteins ranging from 35KD to 85KD antigens including the claimed protein. Characteristics such as protein comprising SEQ.ID.NO: 2,4,6,8 and 10 would be inherent in the preparations of Ristic et al's immunogens.

Since the Office does not have the facilities for examining and comparing applicant's protein

with the product, immunogen of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product, kit comprising antibodies and label and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Status of Claims

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

11/28/03

MARK NAVARRO
PRIMARY EXAMINER